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Congressman Waxman Sends Letter To FDA Requesting Medtronic Sprint Fidelis Information

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POSTED: Tuesday, October 23, 2007

FROM BLOG: [Drug Injury Watch](#) - Prescription Drug Side Effects News and Information from Attorney Tom Lamb

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Committee on Oversight and Government Reform Wants To Know What The FDA Knew About Defibrillator Lead Wire Fractures And When They Knew It (Posted by Tom Lamb at [DrugInjuryWatch.com](#))

On October 22, 2007, as Chairman of the Committee on Oversight and Government Reform, Congressman Henry Waxman (29th District, CA) sent a letter to FDA Commissioner Andrew von Eschenbach about the recently recalled Medtronic Sprint Fidelis defibrillator lead wires.

As characterized on the web site for this [Committee](#), Waxman's letter is "requesting information about the Agency's approval of Medtronic's Sprint Fidelis leads, which are components used in implantable cardiac defibrillators."

A reading of [the October 22, 2007 Waxman letter to the FDA](#), however, reveals that the Congressman is equally interested in learning about when and what Medtronic, Inc. reported to the FDA about the failures of its Sprint Fidelis leads.

In Waxman's October 22 letter we find these requests for information:

- Please provide a chronology of agency actions related to approval of the Sprint Fidelis leads, including, but not limited to, the date of approval for the Sprint Fidelis leads, the PMA or supplement number under which the Sprint Fidelis leads were approved, and any subsequent agency actions or approvals related to the Sprint Fidelis lead.
- Please provide information relating to when and how FDA first became aware of the potential fracture problem and when FDA first proposed that action be taken on this problem to the company. Please also describe the events leading to the voluntary recall, including any communications FDA had with the company regarding the recall and the dates of such communications.
- Please provide the number and types of adverse events that have been reported to FDA since the introduction of these devices, by month. Were all

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adverse events related to fracture problem submitted in a timely manner?

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We look forward to hearing about the responses that Congressman Waxman gets from the FDA about the timing of this recent Sprint Fidelis recall in the context of what Medtronic was telling the agency during the period leading up to the October 14, 2007 FDA recall.

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